EXHIBIT 36

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
College Park, MD 20740

APR 1 - 2014

Samuel S. Epstein, M.D.
Cancer Prevention Coalition
University of Illinois at Chicago
School of Public Health, MC 922
2121 West Taylor Street, Rm. 322
Chicago, Illinois 60612

RE: Docket Numbers 94P-0420 and FDA-2008-P-0309-0001/CP

Dear Dr. Epstein:

This letter is in response to your two Citizen Petitions dated November 17, 1994 and May 13, 2008, requesting that the Food and Drug Administration (FDA or the Agency) require a cancer warning on cosmetic talc products. Your 1994 Petition requests that all cosmetic talc bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer." Additionally, your 2008 Petition requests that cosmetic talcum powder products bear labels with a prominent warning such as: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer." Further, both of your Petitions specifically request, pursuant to 21 CFR 10.30(h)(2), a hearing for you to present scientific evidence in support of this petition.

We have carefully considered both of your Petitions. We are committed to the protection of the public health and share your interest in reducing the risk of ovarian cancer. Current regulations state that cosmetic products shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with a product. FDA may publish a proposal to establish a regulation prescribing a warning statement on behalf of a petitioner if the petition is supported by adequate scientific basis on reasonable grounds.

After careful review and consideration of the information submitted in your Petitions, the comments received in response to the Petitions, and review of additional scientific information, this letter is to advise you that FDA is denying your Petitions. FDA did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer.

For this reason and for the additional reasons described below, FDA is denying your Petitions.

I. Discussion

The basis of your request, throughout both Petitions, can be summarized as comprising three major points:

1. Talc may be associated with asbestos.
2. Talc is a carcinogen based on the findings of a 1993 National Toxicology Program study.
3. Epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

As the points you raise in your Petitions concern the chemistry and toxicology of talc, the epidemiology associated with talc use, and the etiology of ovarian cancer, commensurate reviews were conducted to assess your request.

Chemistry Findings:

Asbestos is a known carcinogen and your first major point is that talc may be associated with asbestos. As evidence that talc cosmetic products contain asbestos, you first cite a 1968 survey of 22 talcum products that found fiber content averaging 19% in all 22 products. This author further concludes that "the fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits …"

You then cite a follow up study from 1971-1975 that examined 21 samples of consumer talcums and powder and concluded that cosmetic grade talc was not used exclusively in these products. This study found the presence of asbestiform anthophyllite and tremolite, chrysotile, and quartz. From these two citations, one may infer that currently available talc-containing cosmetic products are presently contaminated with asbestos, a known carcinogen. Unfortunately, you did not present any original data on the chemical composition of talc currently being used in cosmetics talc products or data linking these findings to currently used talc.

It has been reported in the scientific literature that most talc products in world trade are impure as a result of the geological processes involved in the formation of talc deposits. Further, talc containing asbestos fibers such as tremolite asbestos or chrysotile are sometimes encountered. However, large deposits of high purity, asbestos-free talc do exist and talc purification techniques have been developed which can be used to improve talc quality. Thus, while it has been reported in the past that cosmetic talc has been contaminated with asbestos, it has been also reported that asbestos-free talc deposits do exist. In addition, techniques do exist for the purification of talc in order to improve its quality. You have not provided evidence that asbestos contaminated talc-containing cosmetic products are currently being marketed, since the data submitted is almost 40 years old.

Because safety questions about the possible presence of asbestos in talc are raised periodically, in 2009 FDA conducted an exploratory survey of currently marketed cosmetic-grade raw material talc and finished cosmetic products containing talc. This survey analyzed cosmetic-grade raw material talc from four suppliers out of a possible group of nine suppliers we had requested talc samples from, along with thirty-four talc-containing cosmetic products currently available in the Washington, D.C. metropolitan area for the presence of asbestos. In order to cover as broad a product range as possible, samples identified for testing included low, medium, and high priced products, along with some from "niche" markets. The cosmetic products identified as containing talc included eye shadow, blush, foundation, face powder, and body powder.

The survey found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc or cosmetic products containing talc. While FDA found this data informative, the results were limited by the fact that only four suppliers submitted samples and by the number of products tested. They do not prove that all talc-containing cosmetic products currently marketed in the United States are free of asbestos contamination. As always, when potential public health concerns are raised, we will continue to monitor for new information and take appropriate actions to protect the public health. You may wish to see more on this survey on our website at http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm293184.htm.

Toxicology Findings:

Your second major point is that talc is a carcinogen with or without the presence of asbestos-like fibers. The basis to this claim is that in 1993, the National Toxicology Program (NTP) published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity.

This NTP report concluded that cosmetic-grade talc caused tumors in animals, even though no asbestos-like fibers were found. The report made the following observations:

- There was some evidence of carcinogenic activity in non-asbestiform talc from inhalation studies in male rats based on an increased incidence of benign or malignant pheochromocytomas of the adrenal gland.
- There was clear evidence of carcinogenic activity of talc in female rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland.
- There was no evidence of carcinogenic activity of talc in male or female mice exposed to 6 or 18 mg/cubic meter.

However, this study lacks convincing scientific support because of serious flaws in its design and conduct, including:

- The investigators used micronized talc instead of consumer-grade talc resulting in the experimental protocol not being reflective of human exposure conditions in terms of particle size.

- Investigators conceded that they had problems with the aerosol generation system; whereby, the target aerosol concentrations were either excessive or not maintained during 26 of the 113-122 weeks of the study.
- The study did not include positive and negative dust controls which would have permitted an "exact assessment" of the talc's carcinogenicity relative to the two control dusts.

In light of these shortcomings, a panel of experts at the 1994 ISRTP/FDA workshop declared that the 1993 NTP study has no relevance to human risk.

In addition, we reviewed relevant toxicity literature (consisting of 15 articles from 1980 to 2008), not cited in your Petitions, to determine if there was additional support at this point in time to for your suggested warning label. Scientific literature on studies of acute exposure effects, subchronic exposure effects, chronic exposure or carcinogenicity effects, developmental or reproductive toxicity, and genotoxicity effects were reviewed. As a result of the review of this relevant literature, FDA did not find enough additional support at this point in time for your suggested warning label.

Epidemiology and Etiology Findings:

Your third major point is that epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

After consideration of the scientific literature submitted in support of both Citizen Petitions, FDA found:

1 The exposure to talc is not well-characterized; it is not known if the talc referred to in the scientific studies was free of asbestos contamination; various consumer brands or lots of talc were not identified; and contamination of talc by asbestiform minerals or other structurally similar compounds was not ruled out.

2 Several of the studies acknowledge biases in the study design and no single study has considered all the factors that potentially contribute to ovarian cancer, including selection bias and/or uncontrolled confounding that result in spurious positive associations between talc use and ovarian cancer risk.

3 Results of case-controls studies do not demonstrate a consistent positive association across studies; some studies have found small positive associations between talc and ovarian cancer but the lower confidence limits are often close to 1.0 and dose-response evidence is lacking.

4 A cogent biological mechanism by which talc might lead to ovarian cancer is lacking; exposure to talc does not account for all cases of ovarian cancer; and

5 there was no scientific consensus on the proportion of ovarian cancer cases that may be caused by talc exposure.

6 The conclusion of the International Agency for Research on Cancer that epidemiological studies provide limited evidence for the carcinogenicity of perineal use of talc based body powder and the IARC classification of body-powder talc as group-2B, a possible carcinogen to human beings, is persuasive, but the results of the Nurses' Health Study, a large prospective cohort study, revealed no overall association with ever talc use and epithelial ovarian cancer.

Per the etiology review, approximately 10% of epithelial ovarian cancers are associated with inherited mutations. The remaining 90% of epithelial ovarian cancers are not related to these genetic mutations are non-hereditary. They have been historically classified based on histology as borderline/low malignant potential, serous, endometrioid, mucinous, and clear-cell.

Two theories have historically dominated on the cause of epithelial ovarian cancer and these are the "incessant ovulation hypothesis" and the "gonadotropin hypothesis." In addition to these endogenous factors, the role of exogenous factors via retrograde transport of noxious substances (e.g. carcinogens, particulates such as talc and asbestos, endometriosis and infectious agents) from the vagina and uterus into the Fallopian Tubes and peritoneal cavity have been studied extensively as a possible risk factor for ovarian cancer.

While there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers. However, there has been no conclusive evidence to support causality.

The best evidence for an association or causal relationship between genital talc exposure and ovarian cancer comes from epidemiologic data which show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder. While the growing body of evidence to support a possible association between genital talc exposure and serous ovarian cancer is difficult to dismiss, the evidence is insufficient for FDA to require as definitive a warning as you are seeking.

Request for hearing

In addition to your request for a warning label, you also requested a hearing, under 21 CFR 10.30(h)(2), so that you can present scientific evidence in support of your petitions.

Under this regulation, FDA may deny a citizen petition request for a hearing if the data and information submitted (even if accurate), are insufficient to justify the determination urged. In consideration of your request, we conducted an expanded literature search dating from the filing of the petition in 2008 through January 2014. The results of this search failed to identify any new compelling literature data or new scientific evidence.

Since we find that the data and information are insufficient to justify the determination you request and we did not identify any new compelling literature data or new scientific evidence, FDA is also denying your hearing request.

II. Conclusion

FDA appreciates the goals of the Cancer Prevention Coalition and FDA supports the goal of reducing the rate of ovarian cancer. Although FDA is denying the Cancer Prevention Coalition's petitions for the reasons discussed above, the Agency shares your commitment to the public health.

Sincerely,

Steven M. Musser, Ph.D.
Deputy Director for Scientific Operations
Center for Food Safety
and Applied Nutrition

Drafted: J. Gasper, OCAC, 2/28/14
Comments: L. Katz, OCAC, 3/3/14
Revised: J. Gasper, OCAC, 3/4/14
Cleared: N.Sadrieh, OCAC, 3/4/14
Cleared: LMKatz, OCAC, 3/5/14
Reviewed: FHogue, OCAC: 3/614
Cleared by:Musser:3/13/14
F/T:SRussell, OCAC 3/18/14

EXHIBIT 37

[Letter of proposal to FDA and NIEHS/NIH]

The FDA has legislative responsibility for direct regulation of unsafe ingredients in cosmetics under the Food, Drug and Cosmetic Act. In 1994, as a result of concerns regarding the 1993 NTP animal study and recently published epidemiological studies linking talc and ovarian cancer, the FDA and the International Society for Regulatory Toxicology and Pharmacology co-sponsored a workshop to discuss the issues and to see whether they could arrive at any consensus views on how they should be interpreted. Twenty FDA scientists participated, along with numerous scientists from academia, industry, cancer research institutions, NIEHS, NCI, and other organizations.

At the beginning of the workshop, Dr. John Bailey, Director of FDA's Office of Cosmetics and Colors, presented the "Introduction: Overview - Scope of the Workshop", in which he stated:

> ". . . I think it is reasonable to expect by the end of the workshop to have a discussion or even to reach a consensus of the many scientific and medical experts that are participating in and attending this meeting about the relevance of the recent reports to the safety of talc to human health risks."

At the conclusion of the Workshop, an Executive Summary was prepared by the Rapporteur, Dr. Jelleff Carr (Talc: Consumer Uses and Health Perspectives" in *Reg. Tox. Pharm*. 21(2):211-60 (1995). With regard to the ovarian cancer issue, Dr. Carr explains the consensus that was reached:

> "Following the many issues raised by all presenters, the ensuing discussion generally agreed that while some weak association between talc exposure and ovarian tumors has been reported, it was not sufficient warning for concern."

> "The possibility of an association of talc exposure and ovarian cancer is an important hypothesis of potential public health importance. However, this association remains a research hypothesis whose verification or falsification needs additional study."

> "[E]pidemiologic studies have provided weak and conflicting risk signals for this association and it is unlikely that further studies may prove adequate to raise concern at a level sufficient to warrant regulatory or public health measures."

Indeed, the prediction by the panel that additional epidemiology studies on this subject would prove inadequate to clearly define an association between the perineal application of talcum powder and an increased risk of ovarian cancer was accurate. When NTP began their review of non-asbestiform talc in 2000, eight additional epidemiologic studies were published and evaluated by NTP. The eight additional studies continued to provide weak and conflicting risk signals with no consistent trend by duration or frequency of talc use. Appropriately, the NTP Board of Scientific Counselors Subcommittee concluded that the listing of cosmetic talc was not scientifically justified and voted 7-3 not to list talc (not containing asbestiform fibers).

Since the conclusion of NTP review in 2000, only one additional case-control study has been published (Central Valley of California). Not surprisingly, this additional epidemiological study provided no new information of scientific utility.

Given all this scrutiny during the last decade of "cosmetic talc" and its association with ovarian cancer, Luzenac cannot imagine that an additional review by NTP would result in a reversal of consensus about the scientific validity of this hypothesized association. But given the sensitive nature of this very serious women's health issue and the lingering suspicions concerning cosmetic talc as a possible risk factor, Luzenac would like to propose a remedy to FDA and NIEHS/NIH that would eliminate the need for any further debate and review of this issue.

We propose:

1. The talc industry in the United States will voluntarily phase-out the production and sale of all cosmetic talc products used specifically for consumer dusting powders, body powders, baby powders, and any other loose powder products that might reasonably be anticipated to be used by women for perineal application.

2. In cooperation with domestic cosmetic and pharmaceutical member companies of the CTFA, this product phase-out will occur within XX months of acceptance of these proposals by NTP and FDA.
3. The voluntary withdrawal would not include such products as medicated foot powders where it would not be reasonably anticipated that the product would be used for perineal dusting; nor would the withdrawal include cosmetic talc products sold for make-up, lipstick, eye-shadow and cream foundations where it would not be reasonably anticipated that the product(s) would be used for perineal dusting.
4. The CTFA will assist the FDA in developing an appropriate cosmetic warning label for any dusting or body powders containing talc which are produced or imported after an established date. The label would warn the consumer the product is not to be used for genital dusting and would report of the possible association between genital dusting and ovarian cancer. The warning label would be mandatory.

The result of these proposed actions would:

1. In very short order, virtually eliminate the exposure potential in the general population to dusting powders containing talc. As more and more dusting powders have already been re-formulated with increased levels of cornstarch, the proposed actions would accelerate these product conversions.
2. Eliminating the perineal exposure potential for women suspends the need for NTP to proceed with a review of cosmetic talc. Given the weakness of the science, it is improbable that a listing recommendation would have resulted – meaning the debate on this theorized association would continue unresolved. These voluntary actions proposed by the talc industry and CTFA member companies would end the debate and allow researchers to focus on other more plausible risk factors.

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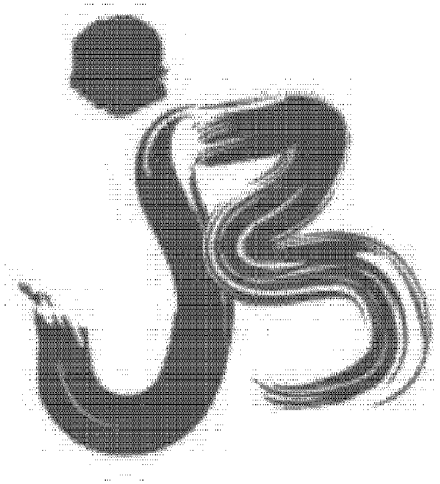
EXHIBIT 38



JOHNSON'S® Baby Powder

2010 Media Recommendation

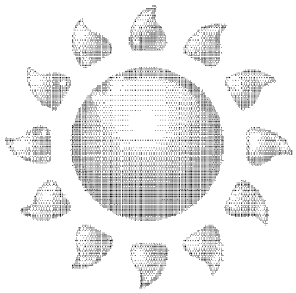
2010 Powder Program Overview

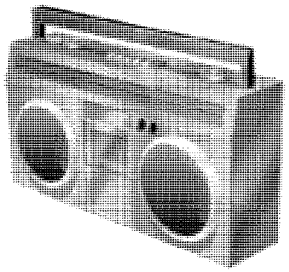
Objective:

- Recruit new and younger users by giving them a compelling reason to use JOHNSON'S® Baby Powder

Key Strategies and Tactics:

- Target overweight women living in hot climates during key summer season
  - Launch campaign with an insertion in People Magazine within weight loss edit and use Weight Watchers Magazine and Everyday with Rachael Ray to target women who are overweight
  - Utilize local or geo-targeted media in hot markets that have a high percentage of overweight consumers





Budget: $555.2M (+12%)

Timing: Q2-Q3

Media Mix: Print: 47%; Radio/Digital: 53%

2

2008/2009 Programs targeted "Women with Curves"

Historic target exhibited distinct behaviors that allowed JOHNSON'S® to reach her easily

- Print in Weight Watchers Magazine
  - Print out-performed norms for Weight Watchers magazine
  - Advertorials explained alternate usages
- Digital on diet sites
  - Digital banners slightly exceeded benchmarks with a .15% CTR
  - Hub on WeightWatchers.com to increase relevance of messaging vs. brand page, resulted in about 24,000 visits
- Sampling at gyms and walking events

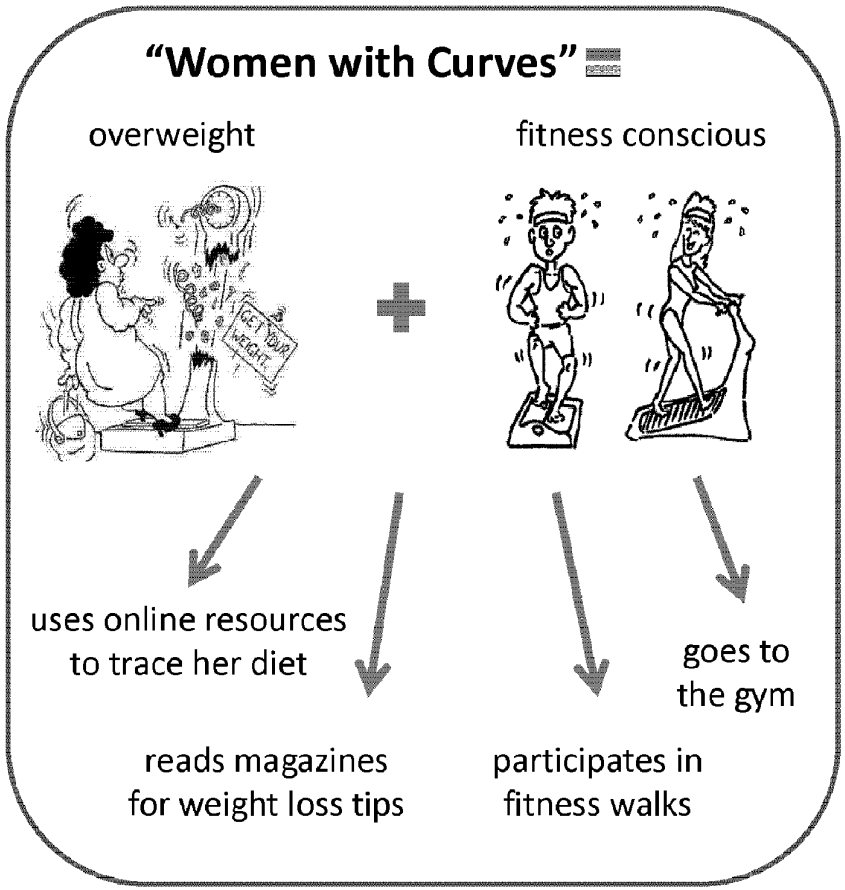
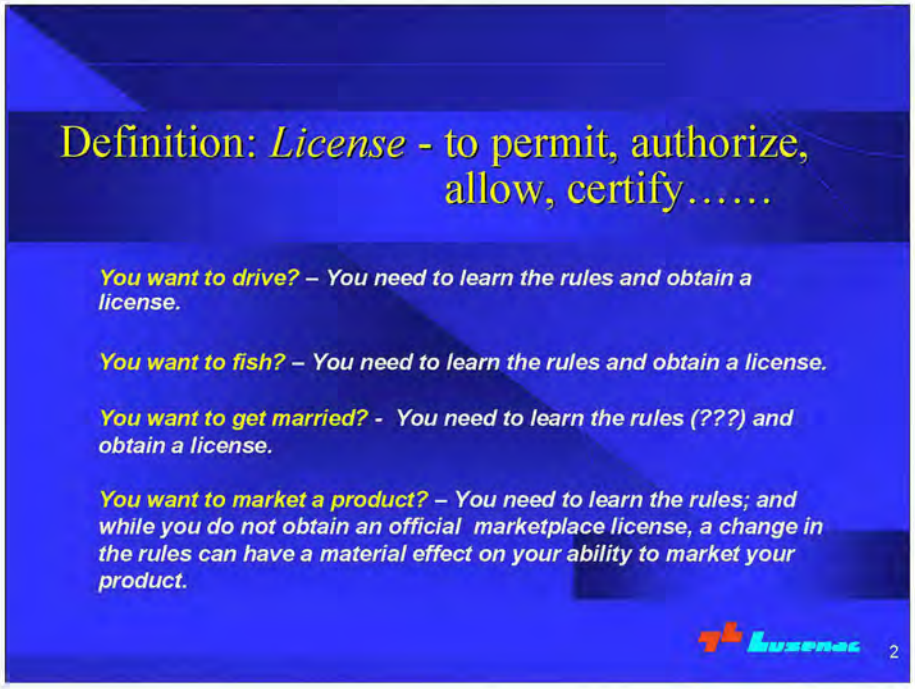


EXHIBIT 39


Definition: *License* - to permit, authorize, allow, certify……
You want to drive? – You need to learn the rules and obtain a license.
You want to fish? – You need to learn the rules and obtain a license.
You want to get married? - You need to learn the rules (???) and obtain a license.
You want to market a product? – You need to learn the rules; and while you do not obtain an official marketplace license, a change in the rules can have a material effect on your ability to market your product.
Luzenac
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IARC
Public Perceptions
F D A
WHMIS
Prop Six-Five
NTP
EU Directive
OSHA
DFG MAK
Litigation Risks
EPA
MSHA
GO
MONOPOLY
Own it all
APPROVED
LICENCE
Want to sell product?
Market place
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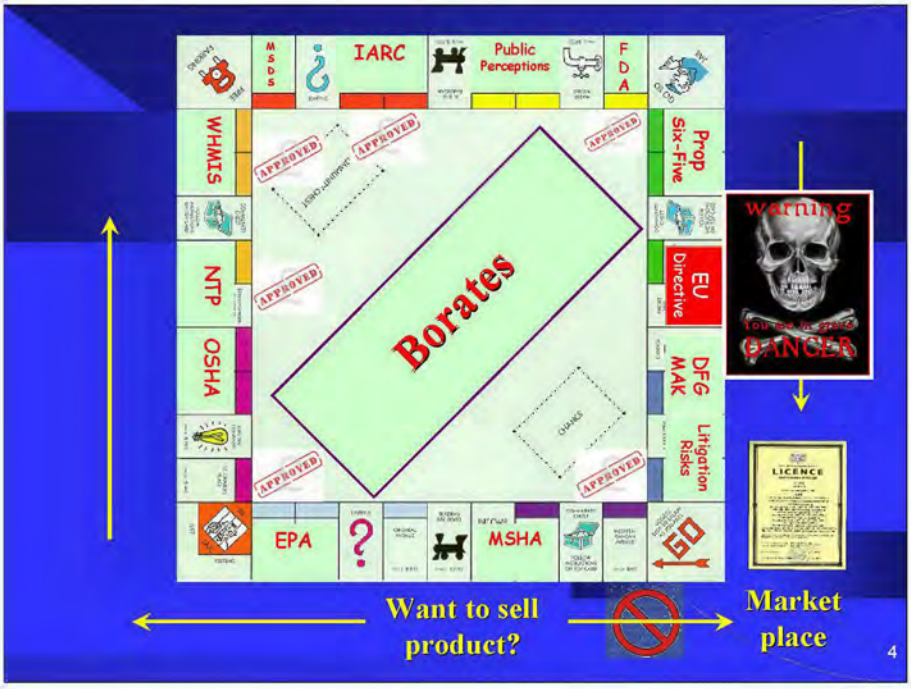
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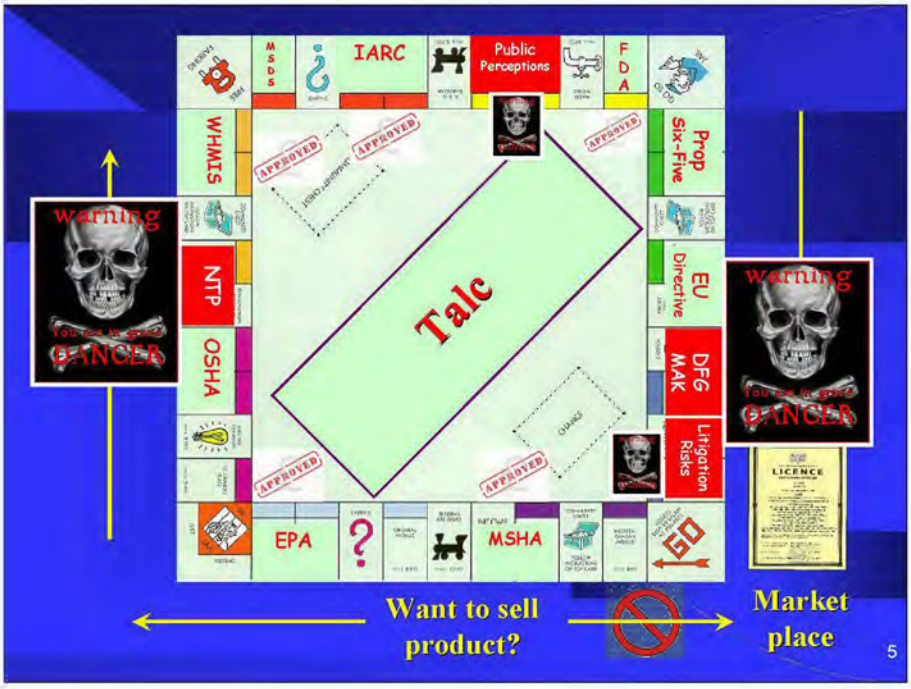
LICENCE
Want to sell product?
Market place
4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warning
DANGER
Want to sell product?
Market place
5


What do we need to do to protect our license to market?
Retain internal regulatory expert(s)
Closely (and regularly) monitor regulatory and agency activities
Utilize Internet tools e.g., "Google News Alerts"
Establish and maintain ties with outside resources e.g., expert legal counsel, "watchdog" services (Center for Regulatory Effectiveness), medical experts with knowledge of your product, legislators, policy makers
Luzenac
6

EXHIBIT 40

Litigation Issues

- February 26, 2002 -

Redacted

Redacted

Redacted

Specific Litigation Issues & Problems

Redacted

Redacted

• **NTP Carcinogenic Listing**. Listing of "talc not containing asbestos fibers" could be potentially devastating from a product liability perspective. [*Plaintiffs attorney: "So Mr. Zazenski, please tell the Court when Luzenac first learned that talc was possibly associated with ovarian cancer?" "When did you first start warning consumers that this association was possible and under study". "Did you not feel a moral and ethical obligation to inform women that the hygienic use of talc may increase their risk for ovarian cancer, or were the profits you were making from mining and selling this potentially dangerous, life-threatening product more important than protecting the health and welfare of the women and children in our society?" Etc. etc. etc.*]

EXHIBIT 41

CFR - Code of Federal Regulations Title 21

The information on this page is current as of April 1 2015.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).[6]

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[Code of Federal Regulations]
[Title 21, Volume 7]
[Revised as of April 1, 2015]
[CITE: 21CFR740.1]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER G--COSMETICS

PART 740 -- COSMETIC PRODUCT WARNING STATEMENTS

Subpart A--General

Sec. 740.1 Establishment of warning statements.

(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

(b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in part 10 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

[40 FR 8917, Mar. 3, 1975, as amended at 42 FR 15676, Mar. 22, 1977]

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7. /scripts/cdrh/cfdocs/search/default.cfm?FAQ=true

8. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm

Page Last Updated: 08/21/2015

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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Silver Spring, MD 20993
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